REMARKS

Appreciation is hereby expressed to Examiner Kennedy for the interview so courteously granted on August 5, 2008. In accordance with that interview, base Claim 17 is hereby amended to more definitely set forth the invention and obviate the rejection. In particular, in Claim 17, the term "consisting essentially of" has been replaced by the expression "comprising", but the weight range of the water swelling polymer has been defined. Support for the amendment of Claim 17 can be found in the Specification on page 13, last paragraph, and page 37, last line, page 42, line 26.

In addition, as discussed with the Examiner during the interview, new claims 26-39 have been presented. Support for the subject matter of new claims 26-35 can be found in the Specification on page 13, last paragraph, page 14, second paragraph, page 17, line 18, page 19, line 25, and page 25, line 23, to page 26, line 8. Further, as discussed in detail with Examiner Kennedy, support for the subject matter of new method claims 36-39 can be found in the Specification on page 25, line 3, to page 26, line 15. The present amendment is deemed not to introduce new matter. Claims 17-39 are now in the application, claims 1-16 having been previously cancelled.

Reconsideration is respectfully requested of the rejection of Claims 17-25 under 35 U.S.C. § 102(e) as being anticipated by Sun, et al. (US Patent 6,678,554).

As previously discussed, in Sun, et al., the polymer Eudragit S or Eudragit E may be used to prevent an increase in the pH of the electrode medium in the fluid reservoir 100 rather than maintaining the pH of the electrode medium. Further, Sun, et al. discloses an active agent reservoir 120 containing an active agent in solution during electrotransport delivery, which is separated by

semi-permeable membrane 108 from the fluid reservoir 110. This is illustrated in Fig. 1 and described in column 8, lines 24-27.

Moreover, the semi-permeable membrane 108 in Sun, et al. inhibits the active agent from contacting the surface of electrode 112 as disclosed in column 8, lines 43-44. On the basis of this disclosure, it is respectfully submitted that one of ordinary skill in the art, with the Sun, et al. reference being considered as a whole, would reasonably conclude that this reference does not disclose using an agent for controlling pH variations in the active agent reservoir 120.

As previously pointed out, in the present invention, there is no semi-permeable membrane installed between an active agent reservoir and a fluid reservoir as in Sun, et al. Rather, the present invention as now claimed herein in amended claim 17 provides a structure for iontophoresis having electrically conductive layer comprised of at least one partially ionized active ingredient, and *0.001-50.0 wt%* of a water swelling polymer having an average molecular weight of 100,000 – 1,000,000 dalton and having a polarity selected considering the dissociation of the active ingredient for controlling pH variation.

According to the present invention, the electrically conductive layer 102 can be directly attached to the skin, as shown in Fig. 1, by using the water swelling polymer having pH dependence solubility and an electrically conductive layer using iontophoresis, without decreasing the drug delivery rate, and thus enabling safe drug delivery to a living body (Specification, page 7, lines 10-14). It is therefore respectfully submitted that these effects of the present invention cannot be derived from the device disclosed by Sun, et al. since the pH variation control in Sun, et al. is not carried out in the active agent reservoir 120, but only in the fluid reservoir 110 as discussed above.

As discussed during the interview, in order to further distinguish from Sun, et al., claim 17 has been amended herein to call for the weight range of the water swelling polymer. As illustrated in Figure 2, when the water swelling polymer is provided in the now claimed weight range, the pH adjusting function of the water swelling polymer within the electrically conductive layer is achieved, thereby providing a high bioavailability of the active ingredient. It is respectfully submitted that Sun, et al. fails to disclose the now claimed weight ranges, and thus fails to anticipate the claims as now amended herein. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 17-25 under 35 U.S.C. § 102(e) as being anticipated by Iga, et al. (US Patent 6,678,554).

In the instant rejection, the Examiner has again predicated the rejection on Iga, et al. on the Doctrine of Inherency, asserting that the pH adjusting function claimed by applicant is inherent in the gel disclosed by Iga, et al. However, it is respectfully submitted that there is no disclosure in Iga, et al. of the use of a partially ionized active ingredient and a water swelling polymer having an average molecular weight of 100,000 – 1,000,000 dalton and having a polarity selected considering the dissociation of the active ingredient for controlling pH variation. For this reason, it is respectfully submitted that Iga, et al. in no way anticipates under 35 U.S.C. § 102(e) the subject matter now called for in the claims herein.

However, as discussed above, base claim 17 has been amended herein to now call for the weight range of the water swelling polymer. As illustrated in Figure 2, when the water swelling polymer is provided in the now claimed weight range, the pH adjusting function of the water swelling polymer within the electrically conductive layer is achieved, thereby providing a high bioavailability of the active ingredient. In fact, the present inventors discovered that by providing

the water swelling polymer in the electrically conductive layer within the claimed weight range, numerous beneficial effects such as optimum delivery rate, ability to adjust pH during energization, stable drug absorption, safe delivery, etc., could be achieved (see Specification, last paragraph).

It is respectfully submitted that Iga, et al. fails to teach or suggest the now claimed electrically conductive layer, as well as the unexpected effects obtained when providing the components thereof in the now claimed weight range. In view of same, it is believed that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

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Date: August 20, 2008